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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,026	05/31/2005	Monika Hedding-Eckerich	ARTHP110US	8757

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EXAMINER	
LEWIS, PATRICK T	
ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
02/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,026	HEDDING-ECKERICH, MONIKA	
	Examiner	Art Unit	
	Patrick T. Lewis	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Response Dated November 26, 2007

1. Claims 1-17 are pending. An action on the merits of claims 1-17 is contained herein below.

2. The rejections of claims 1-6, 8 and 10-16 under 35 U.S.C. 112, second paragraph, has been rendered moot in view of applicant's amendment dated November 26, 2007.

3. The rejections of claims 1-6 and 10-16 under 35 U.S.C. 101 has been rendered moot in view of applicant's amendment dated November 26, 2007.

4. The rejection of claims 7-9 and 17 under 35 U.S.C. 102(b) as being anticipated by Navarro et al. BioFactors (1999), Vol. 10, pages 67-76 (Navarro) has been rendered moot in view of applicant's amendment dated November 26, 2007.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2, 10-12 and 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 2, the phrase "characterized in that uridin-5'-monophosphate is concerned" renders the claim(s) indefinite as it is unclear what applicant intends by said phrase.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Connolly et al. TIPS (1999), Vol. 20, pages 218-225 (Connolly).

Claims 1-6 and 10-16 are drawn to a method of using UMP or CMP for the treatment of affections of the peripheral nervous system and/or for the stimulation of the regeneration of nerves comprising administering UMP or CMP to a patient in need thereof. Claims 7-9 and 17 are drawn to a pharmaceutical composition consisting of UMP or CMP.

Connolly teaches that there are many disorders of pyrimidine metabolism and those that involve an alteration in uridine metabolism have neurological and system effects, which provide insights into the biological activity of uridine and its analogues (page 218). An understanding of how uridine and its nucleotides modulate such vastly complicated biological systems should ultimately lead to the development of new ways for modulating human physiology in both normal and diseased states. Likely targets of therapy include the respiratory, circulatory, reproductive, and nervous systems, and the treatment of cancer and HIV infection.

Pyrimidines, related to purines, can be synthesized de novo within mammals. The ring structure is assembled through a multistep pathway from simple precursors to make the base orotic acid, which is then converted by a multifunctional enzyme, uridine monophosphate (UMP) synthetase, to the nucleotide UMP. Further steps in the anabolic pathway result in the formation of the full complement of pyrimidine nucleotides and nucleic acid components from UMP. See Fig. 1. Uridine nucleotides can be catabolized by ectonucletidases, present on a variety of tissues and cells, including epithelial, endothelial, and neuronal tissues and astrocytes. For example, on rat superior cervical ganglia, ectonucleotidases degrade UTP to UDP, UMP and uridine. A mechanism also exists to reconvert UDP to UTP via an ectonucleoside diphosphokinase.

The few studies of the effects of uridine and uridine nucleotides on the isolated tissues from the nervous system have concentrated mostly on the peripheral nervous system and indicate that both uridine and its nucleotides have direct actions on and are

capable of modulating peripheral nervous system activity (page 221). Clinically, uridine dramatically promoted recovery from the neural degeneration produced by diabetic neuropathy (page 224). These actions of uridine developed over a prolonged period and thus might reflect changes in the metabolism of the patient, either directly within the nerves themselves, or at some other site. Even so, these studies illustrate that uridine can counteract certain pathological disorders and, along with its derivatives, is potentially useful in treating some neurodegenerative disorders.

Connolly differs from the instantly claimed invention in that Connolly teaches the therapeutic benefits of uridine and its nucleotides broadly; however, since this represents a small number of compounds, the use of UMP would have been readily envisioned by one of ordinary skill in the art.

Conclusion

10. Claims 1-17 are pending. Claims 1-17 are rejected. No claims are allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dr. Patrick T. Lewis/
Primary Examiner, Art Unit 1623
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Art Unit 1623

ptl